JUDGE CHIN

File #246949-06/lrc/sl

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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SUSAN MARSA,

Plaintiff,

-against-

WYETH, WYETH PHARMACEUTICALS INC., WYETH-AYERST PHARMACEUTICALS, INC. and WYETH PHARMACEUTICALS,

Defendants.

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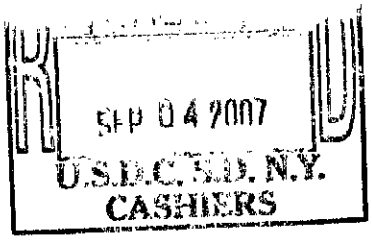
07 CIV. [illegible]

COMPLAINT

Plaintiff Demands Trial by Jury



Plaintiff, by attorneys, FINKELSTEIN & PARTNERS, LLP, as and for the Verified Complaint herein alleges upon information and belief the following:

STATEMENT OF THE CASE

1. This is an action to recover damages for personal injuries sustained by Plaintiff, SUSAN MARSA, as the direct and proximate result of Defendants' wrongful conduct in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of hormone replacement therapy drugs, including Prempro.

PARTIES AND JURISDICTION

2. Jurisdiction exists as against Defendants, WYETH, WYETH PHARMACEUTICALS INC., WYETH-AYERST PHARMACEUTICALS INC. and WYETH PHARMACEUTICALS, pursuant to:

(a) 28 U.S.C. Section 1332, in that Plaintiff, SUSAN MARSA is a citizen and resident of the State of New York, Defendant, WYETH, is incorporated in the State of Delaware

and maintains its principal place of business in the State of New Jersey, Defendant, WYETH PHARMACEUTICALS INC., is incorporated in the State of Delaware and maintains its principal place of business in Pennsylvania, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., is incorporated in the State of Delaware and maintains its principal place of business in Pennsylvania, defendant, and Defendant, WYETH PHARMACEUTICALS, is incorporated in the State of Delaware and maintains is principal place of business in the Pennsylvania, and the amount in controversy exceeds the sum of $75,000.00 exclusive of interest and costs.

(b) Venue is proper in the Judicial District of the Southern District of New York pursuant to 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and a substantial part of the events or omissions giving rise to the claim occurred in this Judicial District.

3. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH has its principal place of business at 5 Giralda Farms, Madison, New Jersey. WYETH is licensed to do business in all states of the United States of America including the State of New York. WYETH regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including, but not limited to hormone replacement therapy drugs, including Prempro. Plaintiff alleges that WYETH does

business in the State of New York and at all times relevant hereto it developed, manufactured, and sold in interstate commerce the aforementioned drugs in the State of New York.

4. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS INC., was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH PHARMACEUTICALS INC. has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. WYETH PHARMACEUTICALS INC. is licensed to do business in all states of the United States of America including the State of New York. WYETH PHARMACEUTICALS INC. regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH PHARMACEUTICALS INC. was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including, but not limited to hormone replacement therapy drugs, including Prempro. Plaintiff alleges that WYETH PHARMACEUTICALS INC. does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH PHARMACEUTICALS INC. either is now or was during the relevant time frame, a subsidiary of Defendant, WYETH, and such Defendant is responsible for all liabilities and obligations to this Defendant.

5. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH-AYERST PHARMACEUTICALS, INC., has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426.

WYETH-AYERST PHARMACEUTICALS, INC., is licensed to do business in all states of the United States of America, including the State of New York. WYETH-AYERST PHARMACEUTICALS, INC., regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH-AYERST PHARMACEUTICALS, INC,. was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including, but not limited to hormone replacement therapy drugs, including Prempro. Plaintiff alleges that WYETH-AYERST PHARMACEUTICALS, INC., does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH-AYERST PHARMACEUTICALS, INC., either is now or was during the relevant time frame, a subsidiary of Defendant, WYETH, and such Defendant is responsible for all liabilities and obligations to this Defendant.

6. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS, a division of WYETH, was and still is a foreign corporation organized under the laws of the State of Delaware. WYETH PHARMACEUTICALS has its principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426. WYETH PHARMACEUTICALS is licensed to do business in all states of the United States of America including the State of New York. WYETH PHARMACEUTICALS regularly conducted, and continues to conduct, its pharmaceutical distribution and sales business within the State of New York and, more specifically, within the geographic jurisdiction of this Court. At all times relevant hereto, WYETH PHARMACEUTICALS was engaged in the business of licensing,

manufacturing, distributing, and/or selling, either directly or indirectly, through third parties or related entities, pharmaceutical products, including, but not limited to hormone replacement therapy drugs, including Prempro. Plaintiff alleges that WYETH PHARMACEUTICALS does business in the State of New York and at all times relevant hereto it developed, manufactured, and sold the aforementioned drugs in interstate commerce and in the State of New York. Further, WYETH PHARMACEUTICALS, either is now or was during the relevant time frame, a subsidiary of Defendant, WYETH, and such Defendant is responsible for all liabilities and obligations to this Defendant.

7. On or about October 29, 2004, Defendant, WYETH, designed, manufactured, marketed and sold the drug Prempro.

8. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH, is engaged in the business of designing, manufacturing, advertising, marketing, and selling hormone replacement therapy drugs, including Prempro, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

9. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH, committed a tortious act inside the State of New York, which caused injury to Plaintiff inside the State of New York.

10. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH, committed a tortious act outside the State of New York, which caused injury to Plaintiff inside the State of New York.

11. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH, regularly does and solicits business and engages in a persistent course of conduct in

the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

12. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

13. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH, manufactured, produced, marketed, sold, distributed, researched, promoted and advertised a hormone replacement therapy drug called Prempro.

14. On or about October 29, 2004, Defendant, WYETH PHARMACEUTICALS INC., designed, manufactured, marketed and sold the drug Prempro.

15. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling hormone replacement therapy drugs, including Prempro, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

16. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS INC., committed a tortious act inside the State of New York, which caused injury to Plaintiff inside the State of New York.

17. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS INC., committed a tortious act outside the State of New York, which caused injury to Plaintiff inside the State of New York.

18. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS INC., regularly does and solicits business and engages in a

persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

19. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS INC., expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

20. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS INC., manufactured, produced, marketed, sold, distributed, researched, promoted and advertised a hormone replacement therapy drug Prempro.

21. On or about October 29, 2004, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., designed, manufactured, marketed and sold the drug Prempro.

22. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling hormone replacement therapy drugs, including Prempro, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

23. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., committed a tortious act inside the State of New York, which caused injury to Plaintiff inside the State of New York.

24. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., committed a tortious act outside the State of New York, which caused injury to Plaintiff inside the State of New York.

25. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

26. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

27. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH-AYERST PHARMACEUTICALS, INC., manufactured, produced, marketed, sold, distributed, researched, promoted and advertised a hormone replacement therapy drug called Prempro.

28. O or about October 29, 2004, Defendant, WYETH PHARMACEUTICALS, designed, manufactured, marketed and sold the drug Prempro.

29. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS, is engaged in the business of designing, manufacturing, advertising, marketing, and selling hormone replacement therapy drugs, including Prempro, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

30. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS, committed a tortious act inside the State of New York, which caused injury to Plaintiff inside the State of New York.

31. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS, committed a tortious act outside the State of New York, which caused injury to Plaintiff inside the State of New York.

32. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

33. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

34. At all times hereinafter mentioned, upon information and belief, Defendant, WYETH PHARMACEUTICALS, manufactured, produced, marketed, sold, distributed, researched, promoted and advertised a hormone replacement therapy drug called Prempro.

FACTUAL BACKGROUND

35. Plaintiff, SUSAN MARSA, developed invasive ductal carcinoma of the right breast and extensive lobular carcinoma of the left breast, requiring a bilateral mastectomy, after taking a hormone therapy drug, including Prempro, HRT products manufactured by Defendants, WYETH, WYETH PHARMACEUTICALS INC., WYETH-AYERST PHARMACEUTICALS, INC. and WYETH PHARMACEUTICALS, (hereinafter referred to collectively as "Wyeth" or "Defendants").

36. Plaintiff brings this action to recover damages for personal injuries against Defendants for their design, promotion, testing, manufacturing, labeling, distribution, promoting

and sale of the following described hormone therapy drugs: a combination of CEE and a synthetic progesterone or progestin, compound name, medroxyprogesterone acetate ("MPA"), sold under the brand name Prempro.

37. A variety of prescribed oral hormone therapy drugs exist and have existed for menopausal women which contain both estrogen and progestins. These drugs can be ingested in combination form (one pill) or separately (i.e., conjugated estrogen and a form of progestin). One of these drugs, Prempro, which is also known by its pharmaceutical name, conjugated equine estrogens/medroxyprogesterone acetate (progestin), is considered a combination hormone therapy because it contains a combination of two hormones, estrogen and progestin.

38. Estrogen therapy refers to use of estrogen alone for hormone therapy. Among the most prescribed brands of estrogen is Defendants' product, Premarin, which is also known by its pharmaceutical name, conjugated equine estrogens.

39. In addition to manufacturing the hormone therapy drug, Prempro, Wyeth and other drug companies manufactured and distributed another hormone drug, medroxyprogesterone acetate, which is a synthetic progestin that when taken concurrently with Premarin constitutes a form of combination hormone therapy that is pharmaceutically equivalent to the Prempro tablet.

40. Hormone therapy medication is marketed to women who are going through menopause. Menopause describes a time in the natural aging process of a woman when her body's production of the natural hormones estrogen and progesterone is dramatically reduced. There are physical consequences to a woman when her levels of estrogen and progesterone drop so dramatically. These consequences include symptoms like mood swings, hot flashes, loss of bone density, depression, irritability, night sweats and forgetfulness. These symptoms range from severe and disabling in some women to a minor inconvenience for other women.

41. In 1942, Ayerst, the predecessor to Wyeth, received approval for Premarin, which is a conjugated equine estrogen made from the urine of pregnant mares. Premarin has remained chemically unchanged until today. Wyeth began marketing its product as a hormone replacement product to replace the natural female hormone estrogen.

42. Defendants have vigorously promoted its menopausal hormone therapy products using a variety of marketing messages that emphasize the use of these medications long-term. Indeed, the 1973 key marketing statement for Premarin was "start her on, keep her on". Even as late as 1991, Wyeth still represented that "protection continued only as long as estrogen therapy continued."

43. To get this message out to the patients and the doctors, Wyeth has used the following marketing methods to promote its products:

a. Sponsoring medical journal articles about the benefits of its products;

b. Detailing /sales representatives calling on and encouraging physicians to prescribe the drugs;

c. Sponsored continuing medical education programs discussing the benefits of its products;

d. Hiring experts in the field to speak to other physicians either one on one or in small group meetings;

e. Press releases;

f. Direct to consumers advertisements about the products;

g. Advertisements directed to physicians in medical journals and materials; and

h. Sponsoring medical and pseudo-medical organizations to make statements supporting the use of the products.

44. Defendants have also extensively represented through the methods listed above, the negative health effects of menopause ranging from symptoms like hot flashes, night sweats

and mood changes to an increased risk of life changing and life threatening conditions like cardiovascular problems, osteoporosis and dementia. Through their marketing and advertising efforts, Defendants have convinced doctors and patients that menopause was not the natural process of aging, but instead turned this process into a disease in need of drug treatment.

45. Wyeth's attempts to disguise menopause as a disease started decades ago. In 1962, Dr. Robert Wilson, a New York gynecologist, published an article in the *Journal of the American Medical Association* ("*JAMA*"), that claimed estrogen taken during menopause could **reduce** breast and genital cancers. A few years later, in 1966, Dr. Wilson published a bestseller book entitled *Feminine Forever*. In *Feminine Forever*, Dr. Wilson recommended estrogen as the "cure" for "the tragedy of menopause." He argued that women who use the drugs "will be much more pleasant to live with and will not become dull and unattractive." In writing about the menopause condition, which he termed the "deficiency disease," Dr. Wilson wrote that "aside from keeping a woman sexually attractive and potent . . . estrogen preserves the strength of her bones, the glow of her skin, the gloss of her hair. Estrogen makes women adaptable, even-tempered, and generally easy to live with." Dr. Wilson asserted that estrogen *prevents* breast and genital cancers, such as endometrial cancer (i.e., cancer of the uterine lining). Unbeknownst to readers, Dr. Wilson was financially supported by Wyeth to write, publish, promote and market this book. While disguised as an independent project, *Feminine Forever* was nothing more than a bestselling promotional piece for Wyeth's estrogen products. There was no reliable science to support Dr. Wilson's assertions or claimed benefits.

46. Soon after the publication of Dr. Wilson's book, Wyeth's sales force began to distribute the book to physicians throughout the country. Wyeth spent thousands of dollars supporting Dr. Wilson's promotional book tour, and sales of Premarin increased dramatically.

47. In 1974 and 1975, Wyeth started a round of advertising that recommended Premarin as an alternative treatment to tranquillizers for the treatment of symptomatic or mild depression caused by menopause. In a print advertisement that Wyeth published in the October 13, 1975 edition of *JAMA*, Wyeth claimed that "tension, irritability, headaches, undue fatigue, depression and insomnia," when caused by declining menopausal estrogen levels, may be relieved with Premarin. Additionally, at the top of the advertisement, in large print, Wyeth advised doctors, "Almost any tranquilizer might calm her down . . . but at her age, estrogen may be what she really needs." The 1975 advertisements stated: "in the treatment of middle-aged depression, there may be one thing to add... Premarin." Again no clinical studies or reliable science supported these representations.

48. In 1977, the Food & Drug Administration ("FDA") issued a statement confirming that estrogen therapy should not be used to treat simple nervousness during menopause and that there was no scientific support for any representation that such therapy could keep a woman feeling young or her skin soft.

49. By the mid-70s more than 30 million prescriptions for Premarin were being written every year, eventually making it the fifth most frequently prescribed drug in the United States.

50. Then the first hormone therapy health epidemic arose. In the New England Journal of Medicine ("NEJM") in 1975, two articles appeared that linked estrogen therapy to a significantly increased risk of women developing endometrial cancer. Quickly physicians stopped prescribing Premarin for women with intact uteri. Estrogen sales plummeted and by 1979, the only approved use of estrogen was for treatment of hot flashes and vaginal dryness.

51. In 1979, Dr. Robert Greenblatt published an article in the *Journal of Geriatrics Society* which reported that "*estrogen related uterine cancer can be avoided if progesterone is added to the regimen*". Wyeth and the other drug manufacturers immediately started promoting combination hormone therapy.

52. In order to obtain a patent on the product, Pfizer Inc. developed a synthetic hormone product called medroxyprogesterone acetate or MPA that was marketed under the brand name Provera. Later, other drug companies began manufacturing this drug. This drug does not have the same chemical or pharmacological effect as the natural hormone progesterone. From the early 1980s until 1995, a common combination prescription was the use of Premarin with Provera. Indeed, in 1985, the Pfizer advertising campaign for Provera was a color advertisement featuring Premarin and Provera as the preferred hormone therapy combination.

53. From the early 1980s until 1995, a common combination prescription was the use of Premarin with Provera, an MPA developed and marketed by Pfizer.

54. Defendants also created alternate estrogen and progesterone products as well as MPA products for use in hormone therapy.

55. In 1985, Wyeth added a new spin to the marketing of hormone therapy drugs by claiming that the drugs could help prevent bone loss. Wyeth hired a public relations firm to create public awareness of osteoporosis and learned that 77% of women had never heard of osteoporosis. As a result, Wyeth's public relations campaign informed women that osteoporosis is a devastating disease and that its estrogen drug, Premarin, could treat it. Soon, their public relations campaign created support for a National Osteoporosis Week and eventually, a National Osteoporosis Foundation (to which Wyeth contributed).

56. Wyeth also sought to claim that hormone therapy drugs, such as Premarin, could prevent or reduce cardiovascular disease. Indeed, Wyeth's sales representatives encouraged doctors to prescribe hormone therapy even if a woman was not having menopausal symptoms because of the therapy's purported cardiac benefits.

57. Wyeth claimed that the cardiac benefits of hormone therapy were proven by the Nurses' Health Study. The Nurses' Health Study was based on questionnaires of almost 122,000 female nurses, including 32,300 post-menopausal women. This study's results were published in 1985 and were clearly impacted by observational and selection bias since the population of nurses were health conscious and generally following better exercise and diet regiments than a general population. Moreover, the participants in the Nurses' Health Study were educated and compliant "patients"—actually nurses—who were more keenly aware of their health conditions and at a lower risk for heart disease regardless of hormone therapy. However, Wyeth ignored this obvious flaw and instead exaggerated the results to support its promotion of Premarin.

58. As a result of Wyeth's marketing efforts, between 1990 and 1995, Premarin became the most frequently dispensed prescription drug in the United States.

59. In approximately 1993, Wyeth distributed a videotape to consumers entitled, "*What every woman should know about Estrogen.*" This videotape claimed to be a "seminar for women" and depicted a female doctor advising women about menopause and hormone therapy. Wyeth's video "seminar" warned of a wide variety of illnesses and ailments purportedly associated with menopause. Among other things, Wyeth represented that estrogen loss causes bones to become "brittle," skin to become "dryer," and sexual intercourse to become "painful and irritating." While Wyeth's video was exhaustive in its warnings about menopause, it glossed over the dangers and risks associated with hormone therapy. In its "*What every woman should*

know about Estrogen" video seminar, Wyeth also represented to women that estrogen provided "long term health protection" and should be continued indefinitely, even after short-term menopausal symptoms, such as hot flashes, had subsided. When a purported consumer inquired how long Premarin should be taken, Wyeth's doctor-spokesperson responded "anywhere from five to ten years in order to get protection from long term problems." And, with regard to breast cancer risks, Wyeth represented to women, through its video "seminar" that the benefits of taking estrogen "far outweigh[ed]" the risks for women unless they faced a particularly high risk of breast cancer.

60. In 1994, Wyeth got approval for its next marketing blockbuster: combination hormone therapy in a single pill. Wyeth's product, Prempro, is an oral medication that combines the estrogenic compound CEE with the progestin MPA in a single pill taken one time per day. A similar Wyeth product containing the same combination of compounds is brand named Premphase. Premphase delivers both CEE and MPA for only part of the monthly regime and then CEE alone without the MPA component for the rest of the month. Wyeth now had multiple hormone therapies in the "Premarin family of products" to market and promote.

61. Soon after introduction of Prempro, Wyeth agreed to fund a four-year heart disease prevention trial, called HERS: Heart and Estrogen/Progestin Replacement Study. Wyeth touted the study as one that would show that Prempro prevented heart disease in women who were at high risk for heart disease. Wyeth was seeking FDA approval of the use of Prempro to prevent or reduce the risk of heart disease. But in 1998, the HERS investigators reported that hormone therapy did not reduce the rate of coronary heart disease events in women with heart disease and in fact dramatically increased the risk of heart disease and heart attack in those

women, especially in the first year. The HERS results were immediately minimized or ignored by Wyeth and its sales representatives.

62. With no actual science to support its assertions, Wyeth continued an aggressive marketing plan with promotion directly to the patients. Beginning in early 1999, Wyeth even distributed a brochure to women through the waiting rooms of physicians' offices, that claimed, "Menopause isn't gone in a flash — its debilitating consequences can affect the rest of your life." The promotional brochure also directed women to "Take a few minutes to think about the rest of your life" and listed a number of conditions which neither Prempro nor Premarin had been approved by the FDA to treat, including Alzheimer's disease, vision problems, tooth loss, heart disease, and colon cancer.

63. In a magazine advertisement that featured model Lauren Hutton, Wyeth made a rash of similar claims, suggesting that its hormone therapy drugs were appropriate for treating or preventing, among other things, memory loss, colon cancer, and age-related vision loss. In the March 19, 2000 edition of *Parade Magazine,* Wyeth spokesperson Lauren Hutton (who was not identified as a Wyeth spokesperson) was asked what she did to look good and feel fit and she answered: "[M]y number 1 secret is estrogen. It's good for your moods, it's good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I'd take the estrogen."

64. A cornerstone of the Wyeth marketing program was promotion of hormone therapy for long-term use of indefinite duration. Specifically, *JAMA* reported that:

> In 2000, 46 million prescriptions were written for Premarin (conjugated estrogens), making it the second most frequently prescribed medication in the United States and accounting for more that $1 billion in sales, and 22.3 million prescriptions were written for Prempro (conjugated estrogens plus medroxyprogesterone acetate). While US Food and Drug

> Administration-approved indications for hormone therapy include relief of menopausal symptoms and prevention of osteoporosis, *long-term use has been in vogue to prevent a range of chronic conditions, especially heart disease.* [Emphasis added.]

65. Wyeth continued to press the FDA to approve the use of Prempro to prevent or reduce the progression of heart disease in post-menopausal women. The FDA did not believe there was sufficient scientific evidence to support such an indication/usage of the drug and denied Wyeth's request without reliable science from a controlled study to support the assertions. Even though the FDA had specifically not approved the use of Prempro for the prevention or improvement of heart disease, Wyeth continued to promote Prempro as having this benefit and even represented to physicians that Prempro reduced cardiovascular mortality by 50%.

66. In the early 1990s, the Women's Health Initiative Study ("WHI") was thus born. Conducted by the National Institutes of Health ("NIH") and supported by Wyeth, this large scale, controlled study was designed to definitively allay any question about Prempro's heart, osteoporosis and mental cognition benefits.

67. While Wyeth waited for the WHI study researchers to collect their data and reach their conclusions, the drug maker's overzealous hormone therapy marketing effort continued. At least until mid-2002, Wyeth distributed a hormone therapy promotional brochure targeted for women consumers. The front cover stated: "Starting your Hormone Replacement Therapy (HRT)" and encouraged a woman to "Say yes to PREMPRO." The brochure contained testimonial statements from women taking Prempro, such as, "I wanted an HRT that was established, time tested, and had a successful track record. I'm delighted with PREMPRO" and "With PREMPRO, I know I've taken action to protect my health — and that's truly empowering." The unbalanced nature of Wyeth's marketing efforts is typified by the inadequate warnings contained in the "Side Effects" section of Wyeth's "Say yes to PREMPRO" brochure.

In the warnings section, Wyeth only relate the risk of uterine cancer (associated with estrogen-only therapy), worsening diabetes, nausea, abdominal pain, irregular bleeding, headache, hair loss, and breast tenderness.

68. On July 9, 2002, the National Heart, Lung and Blood Institute ("NHLBI"), a federal agency and part of the National Institutes of Health, halted the WHI study because the investigators concluded that, under the circumstances, the risks of taking Prempro outweighed its benefits. The scientific papers discussing the results of the WHI study provided the most comprehensive published data evaluating the risk and benefits of this drug combination of CEE and MPA. In July of 2002, the published results of the WHI provided the scientific and medical communities with important (although preliminary) information as to the varied and overwhelming risks associated with hormone therapy. Since July of 2002 there have been a number of additional findings and studies published and other studies evaluating these risks are ongoing currently.

69. The results of the WHI study and other studies like it, contradict the scientific and medical assertions that Defendants had made for decades about their respective products. Defendants told the community of medical physicians who consistently prescribed these medications that the risks of these drugs were minimal and that there were great benefits ranging from symptom relief to the prevention of life threatening medical conditions like heart disease and osteoporosis.

70. The WHI study focused on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in post-menopausal women. Between 1993 and 1998, the WHI enrolled 161,809 post-menopausal women volunteers in the age range of 50 to 79 years. The study was conducted at 40 clinical

centers in the United States and was scheduled to last for 15 years. Participants in the combination therapy arm of the WHI study received Prempro because it contained both the progestin MPA as well as the estrogenic compound Premarin. The Prempro arm of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of this combination pill on the prevention of heart disease and hip fractures, and any associated change in risk for breast and colon cancer.

71. In 2000 and again in 2001, WHI investigators complied with a recommendation from the study's Data and Safety Monitoring Board ("DSMB") to inform participants of a small increase in heart attacks, strokes, and blood clots in women taking hormones. The DSMB, an independent advisory committee charged with reviewing results and ensuring participant safety, found that the actual number of women having any one of these events was small and did not cross the statistical boundary established to ensure participant safety. Therefore, the group recommended continuing the trial due to the still uncertain balance of risks and benefits.

72. At the DSMB's meeting on May 31, 2002, the data review confirmed that the number of cases of invasive breast cancer in the estrogen plus progestin group had crossed the boundary established as a signal of increased risk. The DSMB's May 31, 2002 recommendation to stop the trial was based on the finding of increased breast cancer risk, supported by the evidence of overall health risks exceeding any benefits. On July 8, 2002, participants started receiving letters informing them about the results and telling them that they should stop study medications.

73. The WHI study found that for the Prempro arm, when compared to placebo, there was an overall increased risk of the following adverse events:

a. 41 % increase in strokes;

b. 29 % increase in heart attacks;

c. 100 % increase in venous thromboembolism (blood clots);

d. 22 % increase in total cardiovascular disease; and

e. 26 % increase in breast cancer.

74. The WHI study concluded that the "Overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy post-menopausal US women." The study also found that the combination hormone regimen should not be initiated or continued for primary prevention of coronary heart disease.

75. Because of the importance of the report from the WHI investigators on the estrogen plus progestin study, the study was released early to the public on July 9, 2002, as an expedited article on the JAMA Web site. In commenting on the study's findings, NHLBI Director, Dr. Claude Lenfant, was unequivocal in his own conclusions:

> The cardiovascular and cancer risks of estrogen plus progestin outweigh any benefits—and a 26 percent increase in breast cancer risk is too high a price to pay, even if there were a heart benefit. Similarly, the risks outweigh the benefits of fewer hip fractures.

76. Dr. Jacques Roussow, acting director of the WHI and lead author of the JAMA article, summarized the risks of combination hormone therapy in very straightforward manner as he explained the statistical significance of the study results:

> The WHI results tell us that during 1 year, among 10,000 post-menopausal women with a uterus who are taking estrogen plus progestin, 8 more will have invasive breast cancer, 7 more will have a heart attack, 8 more will have a stroke, and 18 more will have blood clots, including 8 with blood clots in the lungs, than will a similar group of 10,000 women not taking these hormones. This is a relatively small annual increase in risk for an individual woman. Individual women who have participated in the trial and women in the population who have been on estrogen and progestin should not be unduly alarmed. However, even small individual risks over time, and on a population-wide basis, add up to tens of

> thousands of these serious adverse health events. [Emphasis added.]

77. It is now clear that hormone therapy poses substantial health risk with little or no corresponding benefit. These risks include breast cancer, ovarian cancer, heart attacks, strokes, deep vein thromboembolisms, pulmonary embolisms, gallbladder cancer and auto-immune diseases (such as lupus and scleroderma).

78. The connection between hormone therapy usage and breast cancer found in the WHI studies were confirmed by a similar study conducted in the United Kingdom. The August 9, 2003 issue of Lancet reported on the conclusions reached by The Million Women Study – a major research effort funded by Cancer Research UK – confirming that current and recent hormone therapy increases a woman's chance of developing breast cancer and that the risk goes up with duration of use. Scientists at the Cancer Research UK analyzed data from over one million women between the ages of 50 and 64. Researchers found that post-menopausal women using combination hormone therapy were twice as likely to develop breast cancer as non-users (a 100 percent increase). Using the Million Women Study data, it is estimated that hormone therapy has caused more than 100,000 additional and unnecessary breast cancers in the United States alone.

79. Further, the initial WHI results were supplemented on June 25, 2003, by another article published in JAMA. This article confirmed that WHI data found that, in addition to stimulating the growth of breast cancer, combination hormone therapy makes breast tumors harder to detect, leading to dangerous delays in diagnosis. The article reported that breast abnormalities could develop soon after a woman starts taking hormone therapy. Consequently, the study's findings raise questions about the safety of even short-term hormone use. In the same June 2, 2003 issue that reported this study, JAMA also published an editorial by Dr. Peter

H. Gann, a cancer epidemiologist at Northwestern University, who stated that this study represents "further compelling evidence against the use of combination estrogen plus progestin hormone therapy."

80. **Blood Clot risks.** Hormone therapy causes blood clots which, depending on where they occur or end up, result in strokes, heart attacks, thromboembolisms, and pulmonary embolisms. Defendants never adequately or appropriately warned physicians or users that estrogen therapy could cause or contribute to this risk.

81. **Breast cancer risks.** The connection between hormone therapy usage and breast cancer found in the WHI studies were confirmed by a similar study conducted in the United Kingdom. The August 9, 2003, issue of *Lancet,* reported on the conclusions reached by *The Million Women Study* — a major research effort funded by Cancer Research UK — confirming that current and recent hormone therapy increases a woman's chance of developing breast cancer and that the risk goes up with duration of use. Scientists at the Cancer Research UK analyzed data from over one million women between the ages of 50 and 64. Researchers found that post-menopausal women using combination hormone therapy were twice as likely to develop breast cancer as non-users (a 100 per cent increase). Using the Million Women Study data, it is estimated that hormone therapy has caused more than 100,000 additional and unnecessary breast cancers in the United States alone.

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Defendants never adequately or appropriately warned physicians or users that estrogen therapy could cause or contribute to this risk.

82. **Ovarian Cancer risks.** In the same JAMA edition as the publication of the original WHI results, another article appeared related to the risk of long-term use of estrogen-only therapy. This article detailed the National Cancer Institute Study ("NCI") which found that women who took estrogen therapy were more likely to develop ovarian cancer than those not on the hormone. The NCI study is reported at Lacey JV Jr., et al., *Menopausal hormone replacement therapy and risk of ovarian cancer.* (JAMA. 2002 Jul 17; 288(3):334-41.) In the study, NCI researchers followed 44,241 women for 19 years who were taking estrogen therapy only and found that these women had a 60% higher risk of ovarian cancer than women who had never used estrogen therapy. The risk increased proportionately with longer duration of estrogen therapy use. Women who took estrogen therapy for 10 to 19 years had an 80% higher risk than those who did not take the pills. Those on estrogen therapy for 20 years or more were three times as likely to develop ovarian cancer as women who did not take it at all. Most of the NCI participants used Wyeth's brand of estrogen therapy, Premarin. The lead author of the NCI study, Dr. James V. Lacey, summarized the results of his study with the following statement:

> The main finding of our study was that post-menopausal women who used estrogen replacement therapy for 10 or more years were at significantly higher risk of developing ovarian cancer than women who never used hormone replacement therapy.

Dr. Lacey further underscored the implications of his NCI study, by explaining that the findings translate into one or two additional ovarian cancers each year per 10,000 women taking estrogen alone. In 2000, eight million American women took Premarin, the leading estrogen therapy pill. The Lacey study demonstrates that Premarin usage is responsible for up to 1,600 additional ovarian cancer cases in the year 2000 alone.

In October of 2003, the WHI Prempro trial produced a report with findings similar to the NCI study regarding ovarian cancer. In the October 1, 2003 issue of JAMA, WHI researchers reported that combination hormone therapy was associated with increased risk for ovarian cancer and combination hormone therapy caused a 58% increase in ovarian cancer rates.

Defendants never adequately or appropriately warned physicians or users that estrogen therapy could cause or contribute to the development of ovarian cancer.

83. **Auto-Immune Disease risks.** Since 1995, Defendants have known that hormone therapy (including unopposed estrogen therapy) caused a statistically significantly increased risk of auto-immune diseases including Lupus, Scleroderma and Raynaud's Phenomena. Defendants never warned physicians or users of this association or risk.

84. **Gallbladder cancer risks.** Since 1997, Defendants knew (or should have known) that hormone therapy causes a statistically significant increased risk of gallbladder cancer in users. Defendants never warned physicians or users of this association or risk.

85. **Arthritis risks.** Defendants were aware (or should have known) that hormone therapy causes a significant increased risk of incident arthritis. Defendants never warned physicians or users of this association or risk.

86. **Asthma risks.** Defendants were aware (or should have known) that hormone therapy caused an increased risk of newly diagnosed asthma. Defendants never warned physicians or users of this association or risk.

87. **General cancer risk.** In addition to the studies published in *JAMA, NEJM,* and other medical journals, a recent federal agency report also revealed that estrogen could be dangerous to women taking it as hormone therapy. On December 11, 2002, the National Institute of Environmental Health Sciences released its tenth annual report on carcinogens, which confirmed that estrogen is a "known human carcinogen."

88. It is now also clear that hormone therapy provides little real benefit beyond symptom alleviation. For even its approved indications, there were safer alternative medications that provided better results with less risk. Indeed, rather than providing any heart benefit or mental cognition benefit, hormone therapy actually dramatically increases the risk of heart attack and stroke, especially in the first year of use, and reduces a woman's mental functioning. Hormone therapy has now also been associated with hearing loss and osteoarthritis.

89. **Cardiac benefits.** In the August 7, 2003 issue of *NEJM*, the WHI study continued to yield important information regarding the safety of hormone therapy use. The study found that combination hormone therapy does not protect the heart and may even increase the risk of coronary heart disease ("CHD"). Specifically, the WHI study found that combination hormone therapy usage was associated with a 24% overall increase in the risk of CHD (6 more heart attacks annually per 10,000 women using combination therapy) and an 81% increased risk of CHD in the first year after starting combination therapy.

90. **Osteoporosis benefits.** Defendants were aware (or should have known) that other therapies for osteoporosis, including Fosamax, provided better osteoporosis prevention and

treatment benefits with less risk. On May 21, 2003, JAMA published another study studying the efficacy of estrogen plus progestin therapy (e.g., Prempro) for prevention of bone loss in elderly women. The study involved 373 women ages 65 to 90 who had either thinning bones or full-blown osteoporosis and took one of four treatments for three years: (i) combination hormone therapy alone, (ii) a bone-building drug, alendronate (which is sold under the brand name, Fosamax), (iii) combination hormone therapy with Fosamax, or (iv) a placebo. This study found that Fosamax alone was more effective than combination hormone therapy alone in combating osteoporosis. After three years, hipbone density had increased nearly 6 percent in women on hormone therapy with Fosamax, 4 percent in those on Fosamax alone, and 3 percent in the hormones-only group. Yet, Defendants continued to over-promote and exaggerate the hormone drugs' purported benefits.

91. **Increased mental function benefits.** On May 28, 2003, JAMA published another study on the effects of hormone therapy, this time focusing on the risk of Alzheimer's disease and other types of dementia. The study found that combination hormone therapy Prempro doubled the risk of dementia for woman who started hormones at age 65 or older. The dementia study was based on a four-year trial involving 4,532 women at 39 medical centers, where half of the volunteers took placebo pills and half took Prempro. In four years, there were 40 cases of dementia in the Prempro group and 21 in the placebo group. Translated to an annual rate for the population-at-large, the results mean that for every 10,000 women 65 and older taking hormone therapy, there will be 45 cases of dementia a year with 23 of them attributable to hormone use. Dr. Sally A. Shumaker, the director of the dementia study and a professor of public health sciences at Wake Forest University, stated that the study's "clear message is that there's no reason for older women to be taking combination hormone therapy."

92. **Quality of Life benefits.** On March 17, 2003, the New England Journal of Medicine ("NEJM") released a follow-up WHI study which reported that hormone therapy failed to improve the quality of life for menopausal women. The Quality of Life study examined the same pool of 16,000 WHI women and found that hormone therapy drugs do not provide the very benefit that encourages women to take the treatment — that is, to make them feel happier and healthier after menopause. A comparison of women who took hormone therapy to women given a placebo showed those women taking hormones did not report sleeping better or feeling better. The hormone therapy group also did not report less depression or more sexual satisfaction than the placebo group. According to the study's lead author, Dr. Jennifer Hays: "It's just not something that's going to make most women feel better. Even if it reduces your symptoms, that's not going to translate into a meaningful effect on a quality of life."

93. In addition to the studies published in JAMA, NEJM, and other medical journals, a recent federal agency report also revealed that estrogen could be dangerous to women taking it as hormone therapy. On December 11, 2002, the National Institute of Environmental Health Sciences released its tenth annual report on carcinogens, which confirmed that estrogen is a "known human carcinogen." Hormone therapy provides little real benefit beyond symptom alleviation for even its approved indications, there were safer alternative medications that provided better results with less risk. Indeed, rather than providing any heart benefit or mental cognition benefit, hormone therapy actually dramatically increases the risk of heart attack and stroke, especially in the first year of use, and reduces a women's mental functioning. Hormone therapy has now also been associated with hearing loss and osteoarthritis.

94. In the August 7, 2003 issue of NEJM, the WHI study continued to yield important information regarding the safety of hormone therapy use. The study found that combination

hormone therapy does not protect the heart and may even increase the risk of coronary heart disease (CHD). Specifically, the WHI study found that combination hormone therapy usage was associated with a 24% overall increase in the risk of CHD (6 more heart attacks usually per 10,000 women using combination therapy) and a 81% increased risk of CHD in the first year after starting combination therapy.

95. Other theories for osteoporosis, including Fosamax, provided better osteoporosis prevention and treatment benefits with less risk. On May 21, 2003, JAMA published another study studying the efficacy of estrogen plus progestin therapy (e.g., Prempro) for prevention of bone loss in elderly women. The study involved 373 women ages 65 to 90 who had either thinning bones or full-blown osteoporosis and took one of four treatments for three years: (i) combination hormone therapy alone, (ii) a bone-building drug, alendronate (which is sold under the brand name, Fosamax), (iii) combination hormone therapy with Fosamax, or (iv) a placebo. This study found that Fosamax alone was more effective than combination hormone therapy alone in combating osteoporosis. After three years, hipbone density had increased nearly 6 percent in women on hormone therapy with Fosamax, 4 percent in those on Fosamax alone, and 3 percent in the hormones-only group. Yet, Defendants continued to over-promote and exaggerate the hormone drugs' purported benefits.

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21 in the placebo group. Translated to an annual rate for the population-at-large, the results mean that for every 10,000 women 65 and older taking hormone therapy, there will be 45 cases of dementia a year with 23 of them attributable to hormone use. Dr. Sully A. Shumaker, the director of the dementia study and a professor of public health sciences at Wake Forest University, stated that the study's "clear message is that there's no reason for older women to be taking combination hormone therapy."

97. On March 17, 2003, the New England Journal of Medicine (NEJM) released a follow-up WHI study which reported that hormone therapy failed to improve the quality of life for menopausal women. The Quality of Life study examined the same pool of 16,000 WHI women and found that hormone therapy drugs do not provide the very benefit that encourages women to take the treatment, that is, to make them feel happier and healthier after menopause. A comparison of women who took hormone therapy to women given a placebo showed those women taking hormones did not report sleeping better or feeling better. The hormone therapy group also did not report less depression or more sexual satisfaction than the placebo group.

98. According to the study's lead author, Dr. Jennifer Hays: "It's just not something that is going to make most women feel better. Even if it reduces your symptoms, that's not going to translate into a meaningful effect on a quality of life."

99. The warnings and labels provided by Defendants with hormone therapy drugs were inadequate, misleading, and inaccurate. Defendants minimized the risks of these drugs to the prescribing physicians and ultimate users while simultaneously exaggerating the purported benefits. Physicians and patients had no ability to conduct a realistic risk versus benefit assessment.

100. For years, Defendants have promoted hormone therapy as drugs of prevention as well as being safe and effective. The reality is the exact opposite.

101. In the face of the now published independent studies, it is clear that the warnings and labels provided by Defendants were inadequate, misleading, and inaccurate. Defendants minimized the risks of these drugs to the prescribing physicians and ultimate users while simultaneously exaggerating the purported benefits. Physicians and patients had no ability to conduct a realistic risk versus benefit assessment.

102. Defendants provided inadequate warnings concerning hormone therapy as to breast cancer. Indeed, while the Prempro warning mentioned the risk of breast cancer with conjugated estrogens (the Premarin component of Prempro), it also emphasized that, with regard to the effect of added progestins on the risk of breast cancer: "The overall incidence of breast cancer does not exceed that expected in the general population." The WHI study plainly reveals that this warning is false and was known or should have been known by Defendants for decades.

103. Defendants provided inadequate warnings concerning hormone therapy as to blood clots. The Prempro warnings specifically minimized the risks of thromboembolic disorders, pulmonary embolisms and venous blood clots with language such as "the increased risk [of venous thromboembolism] was found only in current ERT [i.e., Premarin only] users", "postmenopausal estrogen use does not increase the risk of stroke" and simply "embolic cerebrovascular events and myocardial infarctions have been reported," without disclosing the true nature of the risk.

104. Defendants provided inadequate warnings concerning hormone therapy as to cardiac damage. For example, under Precautions, the Prempro label acknowledges: "The effects of estrogen replacement therapy on the risk of cardiovascular disease have not been adequately

studied." Nevertheless, Wyeth had long promoted the benefits of long term hormone therapy for cardiovascular disease.

105. Defendants represented that hormone therapy was safe for long-term use. It was not until January 6, 2003, that Wyeth abandoned this long-standing marketing strategy and cautioned physicians in a "Dear Doctor" letter that "estrogens and estrogens plus progestin should be prescribed for the shortest duration consistent with treatment goals. In early June 2003, Wyeth brought their new marketing campaign to the public with a new public relations campaign consisting of full-page advertisements placed in 180 newspapers nationwide. The advertisement, styled as "A Message from Wyeth," revealed Wyeth's abandonment of its long-term strategy of promoting long-term usage of Premarin and Prempro for post-menopausal women for a variety of conditions, stating in part, that:

> Hormone therapy is not a lifelong commitment.... As a result of recent studies, we know that hormone therapy should not be used to prevent heart disease. These studies also report an increased risk of heart attack, stroke, breast cancer, blood clots, and dementia. Therefore, it is recommended that hormone therapy (estrogen, either alone or with progestin) should be taken for the shortest duration at the lowest effective dose.

106. Defendants represented that hormone therapy was safe at the dosages recommended over the years even though Defendants knew for years that lower doses of these medications was just as effective and with less risk. It was again not until 2003, that Defendants cautioned physicians to use the lowest possible dose. Indeed, Wyeth created an entire new marketing strategy called "Go low with Prempro" and launched a new, lower dose combination treatment.

107. Defendants represented that hormone therapy had benefits that were not supported by reliable science and failed to conduct the necessary pre-approval research and post-approval

surveillance to establish the safety of long-term hormone therapy regimen. It was left to independent studies to uncover the serious risks that Defendants knew about (or in the exercise of reasonable care could have known about) these drugs. Defendants never told physicians and patients that no long-term testing had not been performed on these drugs, thereby fraudulently inducing physicians and patients alike to use these products with the false assumption that such drugs had been sufficiently tested.

108. The manufacturers of generic equivalent MPA as well as brand-name Provera were aware that MPA would be prescribed as a part of combination hormone therapy. Indeed, Defendants marketed, promoted and sold their MPA for such combination use, even though synthetic progestin was harmful, defective in design, would exaggerate or accelerate the harmful effects of estrogen, and the combination therapy of estrogen with MPA would be unreasonably dangerous for use. In fact, MPA, when used in combination hormone therapy, has deleterious effects, including increasing the incidence of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer. Even though Defendants knew of these risks, they did not warn consumers of the serious adverse side effects of this form of combination hormone therapy in any of their respective labels or promotion materials.

109. Defendants were aware that MPA would be prescribed as a part of combination hormone therapy. Indeed, Defendants marketed, promoted and sold their MPA for such combination use. Defendants knew, or in the exercise of reasonable care should have known, that the synthetic progestin was harmful, defective in design, would exaggerate or accelerate the harmful effects of estrogen and the combination therapy of estrogen with MPA would be unreasonably dangerous for use. In fact, MPA, when used in combination hormone therapy has deleterious effects, including increasing the incidence of strokes, blood clots, heart attacks, breast

cancers, and ovarian cancer. Even though Defendants knew of these risks, they did not warn consumers of the serious adverse side effects of this form of combination hormone therapy in any of their respective labels or promotional materials.

110. Further, Defendants in their manufacture of generic equivalent and brand-name MPA failed to conduct adequate pre-marketing clinical testing and research to determine the safety of MPA when used in combination with estrogenic compounds like Premarin. Defendants also failed to conduct adequate post-marketing surveillance to determine the safety of MPA when used in combination with estrogenic compounds. Nevertheless, Defendants never disclosed on their respective warning labels that such testing had not been performed, thereby fraudulently inducing physicians and patients alike to use the MPA drugs with the false assumption that such drugs had been sufficiently tested.

AS AND FOR A FIRST CAUSE OF ACTION AGAINST THE DEFENDANTS

111. Plaintiff repeats and reiterates the allegations previously set forth herein.

112. At all times hereinafter mentioned, Defendants were under a duty to exercise reasonable care in the design, manufacture and development of hormone replacement therapy drugs, including Prempro, and in the advertising, marketing, promoting, sale and distribution of such drugs, both directly and indirectly, to ensure that such drugs were not used to treat conditions for which such drugs were not safe and effective or where Defendants knew or should have known that the user could sustain injuries and harm from the drug.

113. Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that

Defendants, directly and indirectly, designed, manufactured, developed, advertised, marketed, promoted, sold and distributed hormone replacement therapy drugs, including Prempro.

114. Defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting hormone replacement therapy drugs, including Prempro, even though such drugs were not safe.

115. Plaintiff used the hormone replacement drugs, including Prempro, in accordance with the direction of her physicians for the treatment of post-menopausal symptoms.

116. As the result of Plaintiff's use of hormone replacement therapy drugs, including Prempro, for the treatment of post-menopausal symptoms, she sustained severe and serious personal injuries.

117. The aforesaid injuries sustained by Plaintiff were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including Plaintiff, on the part of Defendants.

118. At all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of injuries sustained by Plaintiff.

119. At all times hereinafter mentioned, Plaintiff did not contribute to her injuries by reason of any negligence or culpable conduct on her part.

120. At all relevant times, Defendants had and continue to have a duty to exercise reasonable care to properly prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their hormone replacement therapy drugs, including Prempro, which

they introduced into the stream of commerce, including a duty to insure such drugs do not cause users to suffer from unreasonably dangerous or untoward adverse side effects.

121. At all times relevant, Defendants owed a duty to properly warn consumers of the risks, dangers, and adverse side effects of their hormone replacement therapy drugs, including Prempro.

122. Defendants breached this duty by failing to exercise ordinary care in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of their hormone replacement therapy drugs, including Prempro, which they introduced into the stream of commerce, because Defendants knew or should have known that such drugs created an unreasonable risk of harm for those who used the drugs.

123. Defendants knew, or in the exercise of reasonable care, should have known that their hormone replacement therapy drugs, including Prempro, were of such a nature that, if not properly prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold, they were likely to cause injury to those who took their drugs.

124. Defendants negligently provided inadequate and inaccurate warnings and information to the medical community and the public at large, including Plaintiff, by making false representations about the safety of their hormone replacement therapy drugs, including Prempro. Defendants downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of such drugs despite available information demonstrating that their products were likely to cause serious and sometimes fatal side effects to users. Defendants were negligent in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of their hormone replacement therapy drugs, including Prempro, in that Defendants:

a. Failed to use due care in the preparation of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

b. Failed to use due care in the design of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

c. Failed to conduct adequate pre-clinical testing and research to determine the safety of the hormone therapy drugs;

d. Failed to conduct adequate post-marketing surveillance to determine the safety of the hormone therapy drugs;

e. Failed to accompany the hormone therapy products with proper warnings regarding all possible adverse side effects associated with the use of such products and the comparative severity and duration of such adverse effects;

f. Failed to use due care in the development of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

g. Failed to use due care in the manufacture of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

h. Failed to use due care in the inspection of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

i. Failed to use due care in the labeling of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

j. Failed to use due care in the marketing of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

k. Failed to use due care in the promotion of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

l. Failed to use due care in the selling of the hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;

m. Failed to provide adequate training and information to healthcare providers for the appropriate use of the hormone therapy drugs;

n. Failed to warn Plaintiff and the healthcare providers, prior to actively encouraging and promoting the sale of the hormone therapy drugs, either directly or indirectly, orally or in writing, about the following:

- the need for comprehensive, regular medical monitoring to insure early discovery of potentially fatal strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, ovarian cancer, and other adverse side effects;
- the possibility of becoming disabled as a result of the use of the drugs; and
- the adverse side effects associated with the use of the drugs, including, but not limited to, strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, and ovarian cancer; and

o. Were otherwise careless and negligent.

125. Despite the fact that Defendants knew or should have known that the hormone replacement therapy drugs, including Prempro, caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market such products to consumers, including Plaintiff, when safer and more effective methods of countering any health effects of menopause were available.

126. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to exercise ordinary care as described herein.

127. Defendants knew or should have known that the hormone therapy products caused serious side effects. Nevertheless, Defendants continued to market such products by providing false and misleading information with regard to the safety and efficacy of the products.

128. As a result of Defendants' conduct, Plaintiff suffered the injuries and damages specified herein. Defendants are liable to Plaintiff jointly and severally for all general, special, and equitable relief to which Plaintiff is entitled by law.

129. Defendants' actions described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Defendants.

130. As a result of the aforesaid occurrence, the injuries sustained herein resulting therefrom, as aforesaid, Plaintiff suffered extensive monetary and pecuniary losses and there was also incurred and paid out necessary medical and hospital expenses.

131. By reason of the facts and premises aforesaid, Plaintiff sustained damages in the sum of ONE HUNDRED MILLION ($100,000,000.00) DOLLARS, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SECOND CAUSE OF ACTION AGAINST THE DEFENDANTS

132. Plaintiff repeats and reiterates the allegations previously set forth herein.

133. At all times hereinafter mentioned, upon information and belief, Defendants, by directly and indirectly advertising, marketing and promoting the hormone therapy replacement drug Prempro for the treatment of post-menopausal symptoms and by placing this drug in the stream of commerce knowing that this drug would be prescribed for the treatment of post-menopausal symptoms in reliance upon the representations of Defendants, expressly warranted to all foreseeable users of this drug, including Plaintiff, that Prempro was safe and effective for

the treatment of post-menopausal symptoms and in addition were safe for human consumption in general.

134. Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Prempro to all foreseeable users, including Plaintiff, that this drug were safe and effective for the purposes for which such drug had been placed in the stream of commerce by Defendants, including for the treatment of post-menopausal symptoms, and that Prempro was reasonably safe, proper, merchantable and fit for the intended purpose, including for the treatment of post-menopausal symptoms and in addition were safe for human consumption in general.

135. At all times hereinafter mentioned, Plaintiff relied upon the aforesaid express and implied warranties by Defendants.

136. At all times hereinafter mentioned, Plaintiff's use of Prempro prior to and through the time of the above-described injuries were sustained was consistent with the purposes for which Defendants directly and indirectly advertised, marketed and promoted this drug and Plaintiff's use of Prempro was reasonably contemplated, intended and foreseen by Defendants at the time of the distribution and sale of this drug by Defendants, and, therefore, Plaintiff's use of Prempro was within the scope of the above-described express and implied warranties.

137. Defendants breached the aforesaid express and implied warranties because Prempro was not safe for the treatment of post-menopausal symptoms, because Plaintiff's use of this drug for the treatment of post-menopausal symptoms caused or contributed to the injury described herein and because this drug was not safe for human consumption in general.

138. Plaintiff gave appropriate notice to Defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

139. Defendants, through description, affirmation of fact, and promise expressly warranted to the FDA, prescribing physicians, and the general public, including Plaintiff, that Prempro was both efficacious and safe for the intended use. These warranties came in the form of:

a. Publicly-made written and verbal assurances of the safety and efficacy of hormone therapy drugs, including Prempro;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for hormone therapy drugs, including Prempro, which utterly failed to warn of the risks inherent to the ingestion of such products;

c. Verbal assurances made by Defendants regarding hormone therapy drugs, including Prempro, and the downplaying of any risk associated with the drugs;

d. False and misleading written information, supplied by Defendants, and published in the *Physicians Desk Reference* on an annual basis, upon which physicians were forced to rely in prescribing hormone therapy drugs, including Prempro, during the period of Plaintiff's ingestion of hormone therapy drugs, including, but not limited to information relating the recommended dose, administration and duration of the use of the drugs;

e. Promotional pamphlets and brochures published and distributed by Defendants and directed to consumers; and

f. Advertisements.

The documents referred to in this paragraph were created by and at the direction of Defendants.

140. At the time of these express warranties, Defendants had knowledge of the purposes for which hormone replacement therapy drugs, including Prempro, were to be used and warranted it to be in all aspects safe, effective, and proper for such purposes. Defendants' hormone therapy drugs, including Prempro, do not conform to these express representations in that they are neither safe nor effective and use of such drugs produce serious adverse side effects.

141. As such, Defendants' products were neither in conformity to the promises, descriptions or affirmations of fact made about their hormone replacement therapy drugs, including Prempro, nor adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.

142. Defendants breached their express warranties to Plaintiff by:

a. Manufacturing, marketing, packaging, labeling, and selling hormone replacement therapy drugs, including Prempro, to Plaintiff in such a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks to Plaintiff or the prescribing physician or pharmacist, or without so modifying or excluding such express warranties;

b. Manufacturing, marketing, packaging, labeling, and selling hormone replacement therapy drugs, including Prempro, to Plaintiff, which failed to counteract the negative health effects of menopause in a safe and permanent manner and without injury; and

c. Manufacturing, marketing, packaging, labeling, and selling hormone replacement therapy drugs, including Prempro, to Plaintiff, thereby causing Plaintiff serious physical injury and pain and suffering.

143. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered injury and is at an increased risk of developing further injuries and has suffered compensatory and punitive damages in an amount to be proven at trial.

144. Defendants' actions described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Defendants.

145. By reason of the facts and premises aforesaid, Plaintiff sustained damages in the sum of ONE HUNDRED MILLION ($100,000,000.00) DOLLARS, and in addition thereto,

Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A THIRD CAUSE OF ACTION AGAINST THE DEFENDANTS

146. Plaintiff repeats and reiterates the allegations previously set forth herein.

147. At all times hereinafter mentioned, the hormone replacement therapy drug Prempro was not safe for human consumption in general and were not safe for the treatment of post-menopausal symptoms even though Defendants directly and indirectly advertised, marketed and promoted the drug for that purpose.

148. At all times hereinafter mentioned, the hormone replacement therapy drug Prempro was not safe for the purpose for which Defendants, directly and indirectly, advertised, marketed and promoted the drug at the time Defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

149. At all times hereinafter mentioned, upon information and belief, Defendants assumed a strict products liability to users and to persons using the hormone replacement therapy drug Prempro, including Plaintiff, who sustained injuries, harm and damages by reason of the use of Prempro for purposes directly and indirectly advertised, marketed, and promoted by Defendants, including for the treatment of post-menopausal symptoms.

150. Defendants are liable under the theory of Strict Product Liability as set forth in the Restatement (Second) of Torts §402A. Defendants were at all times engaged in the business of manufacturing, creating, designing, testing, labeling, packaging, supplying, marketing, promoting, selling, advertising, warning, and otherwise distributing the hormone replacement

therapy drug Prempro, in interstate commerce, which they sold and distributed throughout the United States.

151. The hormone replacement therapy drug Prempro was expected to and did reach Plaintiff without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned and otherwise distributed.

152. Plaintiff used the hormone replacement therapy drug Prempro in a manner for which it was intended or in a reasonably foreseeable manner.

153. Defendants' hormone therapy caused increased risks of personal injury and harm upon consumption, and therefore constitute a product unreasonably dangerous for normal use due to their defective design, defective manufacture, Defendants' misrepresentations and inadequate facts disclosed to Plaintiff.

154. The hormone replacement therapy drug Prempro manufactured and/or supplied by Defendants was defective due to:

a. Defective design or formulation in that when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation;

b. Defective marketing in that Defendants made inappropriate, misleading, inaccurate and incomplete representations about this product in advertisements, news, commercials, and direct to consumer advertisements. These deceptive marketing representations were made to the FDA, healthcare providers, pharmacists and the public. These deceptive marketing representations were made in order to induce sales and increase profits;

c. Defective design or formulation, in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an

ordinary consumer would expect, and more dangerous than other hormone therapy medications;

d. Inadequate warnings or instructions because Defendants knew or should have known that the product created a risk of dangerous side effects and other related conditions and diseases;

e. Inadequate pre-marketing testing which, if conducted properly, would have revealed the serious problems with this drug prior to the first sale; and/or

f. Inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of dangerous side effects and other related conditions and diseases, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

155. Defendants, therefore, are strictly liable to Plaintiff.

156. Defendants are manufacturers and/or suppliers of the hormone replacement therapy drug Prempro using retail or sample distribution. The drug manufactured and/or supplied by Defendants was not accompanied by proper warnings regarding dangerous side effects and posed potentially fatal health risks associated with the use of hormone therapy drugs in that the warnings given did not accurately reflect the symptoms, scope or severity of such injuries and health risks.

157. Defendants failed to effectively warn consumers, pharmacists, physicians and healthcare providers that even under close medical monitoring, the potential for serious health complications existed, and there was no way to know which patients would suffer such complications.

158. Defendants failed to perform adequate testing in that adequate testing would have shown that the hormone replacement therapy drug Prempro poses significant risks of serious

health events including and related conditions and diseases, with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

159. Defendants knew, or should have known, that the hormone replacement therapy drug Prempro was a dangerously defective product which poses unacceptable risks unknown and unknowable by the consuming public of serious health events and related conditions and diseases. The hormone replacement therapy drug Prempro was defective due to inadequate warnings because after Defendants knew or should have known of the risk of dangerous side effects and potentially fatal health risks, they failed to provide adequate warnings to consumers of the product and continued to aggressively promote and market the dangerously defective drug.

160. As a direct and proximate result Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distribution of the hormone replacement therapy drug Prempro in interstate commerce, Plaintiff has suffered injury and is at an increased risk of developing further injuries and has suffered compensatory and punitive damages in an amount to be proven at trial.

161. Defendants' actions described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Defendants.

162. By reason of the facts and premises aforesaid, Plaintiff sustained damages in the sum of ONE HUNDRED MILLION ($100,000,000.00) DOLLARS, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FOURTH CAUSE OF ACTION AGAINST THE DEFENDANTS

163. Defendants made additional fraudulent misrepresentations and concealment as to the safety and effectiveness of the hormone replacement therapy drugs, including Prempro, which are not detailed herein but will be determined in discovery.

164. Defendants affirmatively and fraudulently misrepresented and concealed that hormone replacement therapy drugs, including Prempro, were safe and effective in the treatment of post-menopausal symptoms, when, in actuality, users, including Plaintiff, were caused to develop breast cancer.

165. Defendants affirmatively and fraudulently misrepresented and concealed that hormone replacement therapy drugs, including Prempro, were safe for human consumption in general, when in actuality, users, including Plaintiff, were caused to develop breast cancer.

166. Defendants knew that hormone replacement therapy drugs, including Prempro, were not safe in the treatment of post-menopausal symptoms and that such drugs not safe for human consumption in general because such drugs caused users to develop breast cancer.

167. Defendants knew that physicians and health care providers would justifiably rely upon defendants' misrepresentations in prescribing hormone replacement therapy drugs, including Prempro, for the treatment of post-menopausal symptoms and in prescribing such drugs for human consumption in general for the treatment of post-menopausal symptoms and that the public, including persons such as Plaintiff, would justifiably rely upon defendants' misrepresentations in using Prempro as prescribed by physicians and health care providers in the treatment of post-menopausal symptoms.

168. Plaintiff justifiably relied upon Defendants' misrepresentations and, accordingly, consumed Prempro as prescribed by her physician for the treatment of post-menopausal symptoms.

169. By reason of Plaintiff's consumption of Prempro in justifiable reliance upon Defendants' fraudulent misrepresentations and concealment, Plaintiff sustained severe personal injuries.

170. At the time the Defendants manufactured, designed, marketed, sold, and distributed hormone replacement therapy drugs, including Prempro, for use by Plaintiff, Defendants knew or should have known of the use for which such drugs were intended and knew or should have known of the serious risks and dangers associated with such use of these products.

171. Defendants owed a duty to prescribing physicians and ultimate end users, including Plaintiff, to accurately and truthfully represent the risks and benefits of hormone replacement therapy drugs, including Prempro. Defendants breached that duty by misrepresenting the risks and benefits of such drugs to the prescribing physicians and ultimate users, including Plaintiff.

172. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered injury and is at an increased risk of developing further injuries and has suffered compensatory and punitive damages in an amount to be proven at trial.

173. Defendants' actions, described above were performed willfully, intentionally, with malice and/or with reckless disregard for the rights of Plaintiff and the public. As such, Plaintiff is entitled to punitive damages against Defendants.

174. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell hormone replacement therapy drugs, including Prempro, owed a duty to provide accurate and complete information regarding these products.

175. Defendants' advertising program, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of hormone replacement therapy drugs, including Prempro, was safe for human use, had no unacceptable side effects, and would not interfere with daily life.

176. Defendants intentionally encouraged consumers and Plaintiff to continue using hormone replacement therapy drugs, including Prempro, for a longer duration than they know or should have known was safe and effective to use such products and at higher dosage levels than necessary.

177. On information and belief, Plaintiff avers that Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of hormone replacement therapy drugs, including Prempro. Defendants, through promotional practices as well as the publication of medical literature, deceived potential users and prescribers of the drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects. Defendants falsely and deceptively kept relevant information from potential users of such drugs and minimized prescriber concerns regarding the safety and efficacy of their drugs.

178. Defendants did not properly study nor report accurately the results of their human animal and cell studies in terms of risks and benefits of their hormone replacement therapy drugs, including Prempro. Defendants also fraudulently and intentionally polluted the scientific

literature related to hormone therapy in general and their hormone drugs in particular. Defendants hired physicians and scientists to write inaccurate and misleading scientific articles for the purpose of creating confusion so as to pollute existing scientific and medical knowledge pertaining to menopausal hormone therapy and their particular products, including Prempro. Defendants then used and relied on these inaccurate and fraudulently prepared scientific papers to defend and justify the marketing, promotions, and labeling of their hormone products. At all times, Defendants knew that what they were publishing or having published was inaccurate and that this information would mislead the members of the medical and scientific communities who were studying or more importantly, prescribing the hormone drugs, including Prempro.

179. The scientific and medical communities were misled as to the true nature of the risk and benefits of Defendants' hormone therapy products, including Prempro, in particular and in general as to the treatment needs and options for the symptoms of menopause. It was not until the publication of the results from the independent study conducted by the WHI that the truth began to be generally available. Even then the doctors in those communities had been so conditioned by the false science published and or funded for years by Defendants that it was difficult for many of those doctors to accept the truth about the risks and lack of benefits associated with these hormone drugs.

180. The misconceptions as to the true risks and benefits of Defendants' hormone drugs, including Prempro, were pervasive throughout the medical and scientific communities due to the marketing methods employed by Defendants that included but were not limited to the following:

a. The publication of fraudulent scientific papers in scientific and medical literature;

b. Providing false and misleading information to doctors during sales and detailing calls at the doctors offices or at medical or scientific conferences and meetings;

c. Funding third-party organizations to disseminate false and misleading scientific and medical information through its publications and its members to physicians and patients;

d. Funding continuing medical education to disseminate false and misleading information to doctors;

e. Paying specialists in the hormone and menopause field to meet with prescribing doctors for the purpose of disseminating false and misleading information about the risks and benefits of the drugs;

f. Providing false and misleading information to the FDA to support inaccurate risk and benefit information contained in the product labeling; and

g. Disseminating direct to consumers advertising to drive patients to their doctors' offices to ask for the drugs based on false and misleading information regarding the risks and benefits of the drugs.

181. In particular, in the materials disseminated by Defendants, they falsely and deceptively misrepresented or omitted a number of material facts regarding their hormone replacement drugs, including Prempro, including, but not limited to, the following:

a. The presence and adequacy of the testing of the hormone therapy drugs, both pre-and post-marketing;

b. The severity and frequency of adverse health effects caused by the hormone therapy drugs;

c. The range of injuries caused by the hormone therapy drugs; and

d. The lack of any reliable science to support representations about the benefits of hormone therapy.

182. As a result of these efforts it was accepted by the medical and scientific communities that these hormone drugs, including Prempro, had a certain risk benefit profile that was shown to be completely false by independent studies including the WHI.

183. Defendants were in possession of evidence demonstrating that the hormone therapy products, including Prempro, caused serious side effects. Nevertheless, Defendants continued to market such products by providing false and misleading information with regard to its safety and efficacy to Plaintiff and her treating physicians.

184. Plaintiff and her treating physicians justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as set out above concerning their hormone therapy drugs, including Prempro.

185. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Defendants. Plaintiff has been misled and denied access to vital information essential to the pursuit of these claims, without any fault or lack of diligence on her part. Plaintiff could not reasonably have discovered the dangerous nature of and unreasonable adverse side effects associated with the use of the combination hormone therapy prior to July 9, 2002, at the earliest.

186. Defendants were under a continuing duty to disclose the true character, quality, and nature of their hormone therapy drugs, including an accurate account of all risk and all benefits. Because of their active concealment of the true character, quality and nature of their hormone therapy drugs, Defendants are estopped from relying on any statute of limitations defense as a bar to Plaintiff's claim.

187. By reason of the facts and premises aforesaid, Plaintiff sustained damages in the sum of ONE HUNDRED MILLION ($100,000,000.00) DOLLARS, and in addition thereto,

Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST THE DEFENDANTS

188. Plaintiff repeats and reiterates the allegations previously set forth herein.

189. Defendants acted, used and employed deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts with intent that physicians and medical providers rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe Prempro, at excessively high dosages, to patients/consumers such as Plaintiff, and causing such patients/consumers to purchase, acquire and use Prempro, at high dosages, as prescribed by their physicians and medical providers, in connection with the sale and advertisement of the drug Prempro, in violation of General Business Law §§ 349 and 350.

190. By reason of Defendants' acts, uses and employment of deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as Plaintiff, were caused to develop breast cancer and sustain actual damages.

191. By reason of the foregoing, Plaintiff sustained actual damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks an increase of the award of actual damages to an amount not to exceed three times the actual damages up to one thousand dollars, and reasonable attorney's fees, as may be found by the Court upon the trial of this Action.

WHEREFORE, Plaintiff demands judgment against the Defendants as follows:

(1) The sum of $100,000,000.00 on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(2) The sum of $100,000,000.00 on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(3) The sum of $100,000,000.00 on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(4) The sum of $100,000,000.00 on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; and

(5) Actual damages sustained on the Fifth Cause of Action, and in addition, Plaintiff seeks an increase of the award of actual damages to an amount not to exceed three times the actual damages up to one thousand dollars, and reasonable attorney's fees, as may be found by the Court upon the trial of this Action, together with interest, costs and disbursements of this Action.

Yours, etc.,

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BY: _____
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